RECEIVED AT DRUG SAFETY SURVEILLANCE
27-FEB-1998-0450

McNEIL CONSUME
FORT WASHI

Individual Safety Report
*3037697-7-00*

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FDA use only

## A. Patient information

| 1. Patient identifier | 2. Age at time of event: | 3. Sex | 4. Weight |
|---|---|---|---|
| [redacted] In confidence | 31 yrs or Date of birth: [redacted] | ( )female (X)male | unk lbs or kgs |

## B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (x) death 8/14/93 (mo/day/yr)
- ( ) life-threatening
- (x) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

| 3. Date of event | 4. Date of this report |
|---|---|
| 8/12/93 (mo/day/yr) | 02/12/98 (mo/day/yr) |

5. Describe event or problem

Physician report of DEATH allegedly associated w/an acetaminophen product in 31yo M presenting to ER 08-12-93 w/ HEMATEMESIS, GI HEMORRHAGE, ACIDOSIS & OLIGURIA. Addl info rec'd from FDA on 12/31/97, upon request to Docket No.77N-094W, Ref.94, Vol.6 of 7: Case doc.#3 is f/u to previously reported Mfr#0171537A. Med records indicate pt presented to hospital(8/12/93) c/o epigastric pain from hit in abd. 3 nts ago & was taking TYLENOL, VICODIN, ibuprofen for pain. Transfer to evaluate hepatic failure. Adm D/O hepatic failure & acidosis. Over course developed HEPATORENAL SYNDROME & died (8/14/93). Final Anatomical Interpretation: massive hepatic NECROSIS, changes c/w drug etiology(acetaminophen), focal steatosis c/w alcohol ingestion; ARDS; cerebral edema (BRAIN EDEMA); acute tubular necrosis. Cause of death: hepatic failure.

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6. Relevant tests/laboratory data, including dates

8/13/93: ethanol=128 mg/dL at 0440, APAP=12.2 ug/mL at 0440, ethanol=66 mg/dl at 1800, APAP=7.4 ug/mL at 1800,(from initial reporter AST=40605),greater than 45K, Bili=10.5, LDH=48800, creatinine= 3.7, pH=7.2, pO2=44, (See Sect.B.7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

8/11/93 Rec'd Sodium Brevitol® & meperidine for dental extraction; recent hx of being punched in the abdomen; hx of alcohol abuse (1/5 liquor(whiskey) per day, until 3 days PTA); malaria 9 yrs ago; asthma; Cont'Sect.B.6: pCO2=77; Alk Phos=245, LD=28602, AST=25158, PT & PTT were greatly elevated, 4hrs post admission:amylase=208 IU/L; lipase=1146

FDA Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 an unknown TYLENOL® acetaminophen product
#2 VICODIN® (See Sect.C.10)

| 2. Dose, frequency & route used | 3. Therapy dates (if unknown, give duration) from/to (or best estimate) |
|---|---|
| #1 unknown dose, oral | #1 8/09/93-8/12/93; 3 or 4 days |
| #2 unknown dose, orally | #2 8/09/93-8/12/93; 3 or 4 days |

| 4. Diagnosis for use (indication) | 5. Event abated after use stopped or dose reduced |
|---|---|
| #1 toothache | #1 ( ) Yes ( ) No (X) N/A |
| #2 toothache | #2 ( ) Yes (X) No ( ) N/A |

| 6. Lot # (if known) | 7. Exp. date (if known) | 8. Event reappeared after reintroduction |
|---|---|---|
| #1 | #1 | #1 ( ) Yes ( ) No (X) N/A |
| #2 n/a | #2 n/a | #2 ( ) Yes ( ) No (X) N/A |

9. NDC # - for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
VEETIDS® 500 mg daily; PRIMATENE®; unknown quantity of ethanol; toxicology positive for marijuana and opiates; also positive for aspirin
cont'Sect.C.#3 Ibuprofen, unknown dose,po

## G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)
- ( ) foreign
- ( ) study
- ( ) literature
- ( ) consumer
- (X) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 12/31/97

5. (A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product ( ) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
( ) 5-day (X) 15-day
( ) 10-day ( ) periodic
( ) Initial (X) follow-up # 1

8. Adverse event term(s)
DEATH
HEMORRHAGE GI
HEPATORENAL SYN
ACIDOSIS
HEMATEMESIS
OLIGURIA
NECROSIS
EDEMA BRAIN

9. Mfr. report number: 0171537A

## E. Initial reporter

1. Name, address & phone #
[redacted] Esq.
[redacted] Avenue [redacted]

| 2. Health professional? | 3. Occupation | 4. Initial reporter also sent report to FDA |
|---|---|---|
| ( ) Yes (X) No | attorney | (X) Yes ( ) No ( ) Unk |